

K073426 (pg 1 of 2)

510(k) Summary

Cayenne Medical, Inc.
AperFix Interference Screw

ADMINISTRATIVE INFORMATION

FEB 19 2008

Manufacturer Name: Cayenne Medical, Inc.
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Scottsdale, AZ 85260
Telephone (480) 502-3661
FAX (480) 502-3670

Official Contact: Kereshmeh Shahriari
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Scottsdale, AZ 85260
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Telephone (480) 502-3661
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DEVICE NAME

Classification Names: Screw, fixation, bone

Trade/Proprietary Name: AperFix™ Interference Screw

Common Name: Bone screw

DEVICE CLASSIFICATION

FDA has classified bone screws as Class II devices (21 CFR 888.3040). The product code for screw, fixation, bone is HWC. These devices are reviewed by the Orthopedic Joint Devices Branch.

INTENDED USE

The AperFix™ Interference Screw is intended for use with bone-patellar tendon-bone (BPTB) grafts to provide fixation during arthroscopic or open ACL reconstruction procedures.

DEVICE DESCRIPTION

The Cayenne Medical AperFix™ Interference Screw is intended for the bone-patellar tendon-bone (BPTB) reconstruction of the anterior cruciate ligament (ACL). During an ACL reconstruction procedure, BPTB grafts are fixed to the femur and tibia utilizing the AperFix™ Interference Screw. BPTB grafts are typically harvested from the patient's ipsilateral leg, but cadaveric grafts are also acceptable. The AperFix™ Interference Screw is packaged STERILE. The AperFix™ Interference Screw provides interference fixation of the BPTB graft within the femoral and tibial tunnels.

The AperFix Interference Screw will be supplied sterile. Sterilization will be accomplished by means of Co⁶⁰ gamma irradiation at a dose of 25-40 kGy.

Mechanical testing was performed on the AperFix Interference Screw. It was shown that pull-out strength is significantly higher than that of a predicate interference screw.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the AperFix™ Interference Screw is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 19 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cayenne Medical, Incorporated
% Ms. Kereshmeh Shahriari
Directory of Quality Assurance & Regulatory Affairs
16597 North 92nd Street, Suite 101
Scottsdale, Arizona 85260

Re: K073426

Trade/Device Name: AperFix™ Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 4, 2007
Received: December 5, 2007

Dear Ms. Shahriari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

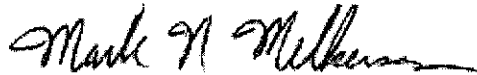
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073426


Device Name: AperFix™ Interference Screw

Indications for Use:

The AperFix™ Interference Screw is intended for use with bone patellar tendon bone (BPTB) grafts to provide fixation during arthroscopic or open ACL reconstruction procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073426